

k031154
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**SUMMARY OF SAFETY AND EFFECTIVENESS
Sintea Biotech Traumafix System with Schanz Screw**

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k) premarket notification is in accordance with 21 CFR 807.87 and the SMDA.

1. Submitter of 510(k)

JUN 24 2003

Marianne Grunwaldt
Regulatory Affairs Specialist
Sintea Biotech, Inc.
407 Lincoln Road Ste 10L
Miami Beach, FL 33139

Telephone: (305) 673-6226
Facsimile: (305) 673-3312

2. Name of Device

2.1 Trade / Proprietary Name

Sintea Biotech Traumafix System with Schanz Screw

2.2 Common / Usual Name

Fixation Pins

2.3 Classification Name

Smooth or threaded bone fixation fastener (21 CFR 888.3040)

3. Applicant / Manufacturer

Sintea Biotech, Srl.
Via Aquileia 33/H Baranzate
Milano, Italy

Telephone: 011-39-02-38204222
Facsimile: 011-39-02-38204230

4. Reason for Submitting the 510(k)

Sintea Biotech, Inc. intends to commercially distribute a modified version of its previously 510(k)-cleared Traumafix external fixation system. Sintea Biotech wishes to distribute the Traumafix system with an additional Schanz screw component.

5. Device Description

Schanz's screws are components of the Sintea Traumafix (TFX) system and were developed for external fixation according to Ilizarov's principle to treat severe articular fractures, pseudo-arthritis and limb lengthening. The purpose of the TFX system is to obtain a safe, non-rigid fixation, to stimulate bone re-growth. The function of the Schanz's screws is to transfer axial forces between the bones and the rings of TFX system, in a mono-lateral construct. The Schanz's screws

are available in three different diameters (4.0, 5.0, 6.0 mm) and three different lengths (120, 150, 180 mm). They consist of round bars having a thread at one end and a square tang at the other end to allow for easy screwing. Furthermore, the threaded length may be interrupted to allow bi-cortical fixation. The special shape of the threaded extremity makes the screws self-tapping.

Mechanical tests of the Sintea Biotech Traumafix System with Schanz Screw demonstrate that the device is safe and effective for its intended use.

6. Predicate Device Identification and Statement of Technological Comparison

The Sintea Biotech Traumafix System (K022065, Decision Date 08/06/2002) was found to be substantially equivalent to referenced predicate device(s). This new 510(k) submission seeks to add a Schanz Screw component to the approved system. Other marketed external fixation systems that are similar to the Traumafix System incorporate screw components into their design. One such system, Howmedica Osteonics Corp.'s Apex Fixation Pins (K011136, Decision Date 05/04/2001, and K861766, Decision Date 07/08/1986) is the predicate device for this submission. The Sintea Biotech Traumafix System's Screw and Howmedica Osteonics Corp.'s Apex Fixation Pins are similar in that:

- the devices have the same intended use and indications for use
- the screw components are made of the same materials
- the external portion of the devices is made of the same material
- the mode of fixation of the devices is identical
- the devices have similar form, function, components, instruments, geometry, features and packaging
- the devices have the same labeling and are both sold non-sterile with sterilization required prior to use.

In summary, the use of QSR-based process controls, testing standards, material standards and similarities to the predicate device establish that the Sintea Biotech Traumafix System's with Schanz Screw is equivalent to Howmedica Osteonics Corp.'s Apex Fixation Pins and that it is safe and effective for its intended use.

7. Intended Use

The Intended Use of the Sintea Biotech Traumafix (TFX) System is to obtain a safe, non-rigid fixation, to stimulate bone re-growth. The function of the Schanz Screw is to transfer axial forces between the bones and the rings of TFX system, in a mono-lateral construct.

8. Indications for Use

The Sintea Biotech Schanz Screw is indicated for use in the external fixation of bone.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2003

Ms. Marianne Grunwaldt
Regulatory Affairs Specialist
Sintea Biotech, Inc.
407 Lincoln Road, Suite 10L
Miami Beach, FL 33139

Re: K031154

Trade/Device Name: Sintea Biotech Schanz Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: April 10, 2003
Received: May 28, 2003

Dear Ms. Grunwaldt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

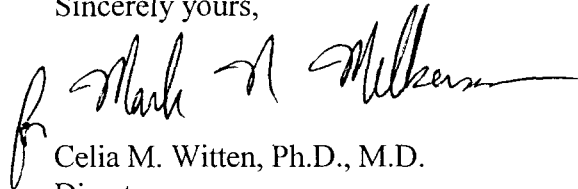
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K031154

Device Name: Sintea Biotech Schanz Screw

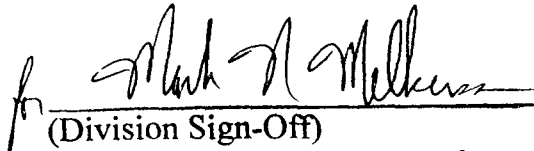
Indications For Use:

The Sintea Biotech external fixation screw is indicated for use in the external fixation of bone.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031154